2

BEFORE THE DEPARTMENTAL APPEALS BOARD
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:	*	FOOD AND DRUG ADMINISTRATION
KORANGY RADIOLOGY ASSOCIATES, P.A., t/a BALTIMORE IMAGING CENTERS,	*	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PANELTY
	*	FDA Docket: 2003H-0432
And	*	
AMILE A. KORANGY, M.D.	*	

* * * * * * * * * * * * *

RESPONDENTS' MEMORANDUM

The following specific Exceptions of Respondents are herein addressed:

A. Partial Summary Decision.

1. The "Discussion of Law," (page 8), and the "Conclusions and Order," (page 10), both conclude that each Respondent is liable for 192 violations of 42 USC §263b(h)(3)(D). Respondents believe that, having determined that each Respondent was liable for one violation of 42 USC §263b(h)(3)(A), the Administrative Law Judge ("ALJ") was precluded from finding violations of §263b(h)(3)(D).

Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) as a basis for levying fines that are based solely on alleged violations of 42 USC 263b(h)(3)(A), and are therefore limited by statute to a total of $10,000.00 for "failure to obtain a certificate." Therefore, 192 counts against each Respondent should be denied on this basis.

The pertinent parts of Section (h)(3) are provided:

> "(3) Civil money penalties
> The Secretary may assess civil money penalties in an amount not to exceed $10,000 for –
> (A) failure to obtain a certificate as required by subsection (b) of this section, ...
> (D) each violation, or for each aiding and abetting in violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate."

Clearly, Congress singled out, in subsection (3)(A), the failure to obtain a certificate, as an offense to be treated separately, as it is the only specific offense that merited its own subsection of the Act, or even any specific mention in the civil money penalties section of the Act. Clearly, Respondents are each charged with a violation of (3)(A), as operation of mammography equipment accurately describes the acts that create the offenses alleged in the Complaint in the instant case.

Complainants have attempted to utilize subsection (3)(D) to create 384 (192 x 2) additional punishable offenses out of the same act that created the alleged violation of subsection (3)(A). If the Respondents did operate mammography equipment without a certificate, their offenses are fully described by the express terms of subsection (3)(A). Complainants would presumably read subsection (3)(D) to allow additional penalties for "each violation" of the FDA regulations – read each time a piece of equipment is used without certification being properly in place. This argument fails. Subsection (3)(A) does not indicate that the fine is to be levied for independent acts or repeated acts, but only for "failure to obtain a certificate." There is no indication, unlike in the subsequent provisions of the Act, of Congressional intent for the issuance of multiple fines for this offense. Subsections (h)(3)(B), (C) and (D), each provide for a fine for "each failure" or "each violation." Subsection (h)(3)(A) is uniquely silent in that regard. Accordingly, once a Respondent is charged with a violation of (3)(A), there can be no violations of (3)(D) based upon the "failure to obtain a certificate." Subsection (3)(D) covers violations beyond those previously specified in section (h), and does not repeat them. To read section (h)(3)(D) as creating multiple violations of the failure to obtain a certificate would render section (h)(3)(A) as completely superfluous, and that is an impermissible reading of a section of federal statute. The Center's case has taken one violation of (h)(3)(A), and magically turned it into 384 violations, despite clear Congressional intent to the contrary.

B. Initial Decision.

1. The ALJ denied Respondents' argument to the effect that the proposed Civil Money Penalties ("CMPs") were issued illegally because of a lack of compliance with the provisions of 42 USC §263b(h)(4), which require that the Secretary develop and implement procedures with respect to when and how each of the sanctions contained in the Mammography Act will be imposed. (Pages 2 and 3).

The federal statute providing authority for FDA regulation of mammography equipment is 42 USC 263b (the "Mammography Act"). The authority for the issuance of CMPs for non-compliance with the Act and its implementing regulations is 42 USC 263b(h), subsection (4) of which requires that "[t]he Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under (the preceding) paragraphs (1) through (3)."

It is uncontroverted, and in fact, admitted by FDA, that the agency has never issued guidance with respect to the requirement to develop and implement procedures for when and how the sanction authority that includes the use of CMPs is to be utilized. Testimony of Michael P. Devine, Tr. at p. 13. In plain English, the FDA has ignored the statutory requirement that it develop and implement guidance regarding the issuance of CMPs. There exist no rules,

policies or procedures with respect to the issuance of such fines. The FDA has left the "when and how" of the use of such sanctions to arbitrary determination, despite the clear statutory mandate to the contrary.

As a result, the imposition of CMPs in this case is illegal. The FDA's authority is granted by the statute, and expressly limited by the statute. That the issuance of fines without any standards is, by definition, arbitrary and capricious, will be addressed in the next section. The point herein being made is that FDA had no legal authority to issue fines without the requisite standards having been developed and implemented.

As a subsidiary matter, it is to be noted that 42 USC 263b(h)(4) also requires the development of procedures to provide for notice to the "owner or operator" of the facility. In the instant case, delivery of notice was accepted upon evidence that it had been "received by the facility," (Testimony of Michael P. Devine, Tr. at p. 17), and it did not matter "who" received it. Id. at 18, 19 and 20. Despite the fact that Dr. Korangy was personally charged with $1,800,000.00 in fines, no effort was made to restrict delivery to him, or to ensure that he actually received a copy of the delivered document intended to notify him of the existence of a violation that required remediation. Whether or not this is considered "fair," it does not meet the statutory mandate to develop procedures to provide notice to the "owner or operator" of the facility.

2. The ALJ denied Respondents' argument to the effect that the FDA (referred to as "the Center" in the applicable regulations) did not meet its burden of proof to establish the appropriateness of the CMPs sought in this case. (Page 3). The regulations, at 21 CFR 17.33, place that burden of proof on the Center.

Governing federal regulations, at 21 CFR 17.33, mandate that "the Center" must, at hearing, prove the appropriateness of the penalties issued, by a preponderance of the evidence. This was not done in the instant case. The following is a discussion of what factors the Center "proved" in the instant case with respect to the appropriateness of 386 counts of $10,000.00 maximum fines:

a. FDA did not consider mitigation. The fact that Respondents ordered a new machine even before being told that their existing machine would not warrant recertification was not considered relevant. Testimony of Michael P. Devine, Tr. at p. 24. Further, there was no FDA consideration given to the uncontroverted fact that Respondents were reimbursed less than their expenses for the provision of mammography tests. Korangy Direct Testimony, at p.4; Exhibit R- 4.

b. FDA testified that it considered Respondents' ability to pay, but indicated that the only consideration given to that issue was to "determine" that Respondents could indeed afford $3,800,000.00 in fines because they had "several different locations." Id., at 25. No other factors or information regarding ability to pay were considered before issuing the CMPs. Id., at 26.

c. FDA did consider the length of time of violation and the number of violative procedures in determining the appropriateness of the penalty. Id., at 30. However, this testimony, if not false, is patently bizarre, in view of the penalties issued more recently by FDA in In Re Ecumed Health Group, et al, FDA Docket: 2004H-0322. (Admitted through Judicial Notice - See ALJ Order of October 7, 2004.) In that case, filed by FDA on July 19, 2004, the respondents were accused of performing 1,201 inappropriate procedures, over a time period spanning 17 months. Compare to the instant case, where the charges consist of 192 procedures spanning a two-month period. In both cases, the FDA issued, to each Respondent, one $10,000.00 fine for performing procedures without current certification. In the instant case, however, each procedure also brought a $10,000.00 fine against each Respondent. In Ecumed, the per-procedure fine was $1,000.00. Accordingly, in Ecumed, considerably more egregious alleged violations (in both number and time) brought penalties a mere tenth of those levied against Dr. Korangy and Korangy Radiology Associates, P.A. ("Intent" is not a factor favoring distinction, as evidenced by Paragraphs 30 and 31 of the FDA compliant in Ecumed, which charged the respondents in that case with knowledge of the alleged violations.) Therefore, FDA testimony in the instant case that the agency "considered" the length of time of violations and number of procedures in determining the penalty is not credible, and in fact, is meaningless.

No evidence was presented to indicate that any other factors were considered by FDA in issuing the fines in the instant case. Accordingly, the Center has not met its regulatory burden to demonstrate, by a preponderance of the evidence, that the penalties issued in this case were appropriate. Instead, the evidence presented by FDA clearly indicates that the maximum penalties that FDA believed were allowed by law were levied, and no serious consideration was ever (prior to or during the hearing) given to the "appropriateness" of such amounts, despite the requirement of 21 CFR 17.33 for the Center to prove such appropriateness.

3. The ALJ fashioned an alternative sanction (penalties reduced from those initially imposed). (Pages 8 and 9). This was done through the rejection of Respondents' argument that the ALJ had no power to revise the proposed sanctions, given the Center's failure to (a) meet the burden of proof requirements of 21 CFR 17.33, and (b) produce the procedures required by 42 USC §263b(h)(4). (Page 3). The ALJ offered no rationale to justify the modified CMPs he has recommended, other than to state that the Center, in its Post-Hearing Brief, has expressed the willingness to modify the CMPs imposed by the FDA to $3,000 per "violation."

4. The ALJ rejected, without any consideration, Respondents' arguments that, to be rational (and not arbitrary and capricious), the penalties sought must be proportional to penalties sought in extremely similar cases. (Page 4). The basis for the rejection of this argument was the statement by the ALJ that "since a determination of CMP's necessarily involves consideration of only those factors present I each individual proceeding, Respondents' comparison is totally irrelevant." Id. This was a peculiar conclusion, given that the entire charging document in the Ecumed case had been accepted into evidence in our case below. Clearly, all relevant factors were in the record and available for scrutiny and comparison, and argument if appropriate. Just as clearly, the ALJ dismissed any concern regarding the arbitrary and capricious nature of the Center's position without any consideration whatsoever.

5. The ALJ determined that Respondents have the ability to pay the CMPs sought by the FDA in the instant case through the acceptance of inappropriate evidence over the Motion to Strike of the Respondents. (Page 5 through 8). The ALJ called for simultaneous post-hearing briefs, denied Respondents' attempt to answer allegations made in the Center's brief, and refused to strike voluminous documentary "evidence" accompanying the Center's post-hearing brief. (See ALJ's Order of December 9 and 15 2004). The ALJ would not accept a two-page response because reading it appeared to be too much of a burden, yet the ALJ refused to strike evidence that was not presented before or during the hearing, and pertaining to which the ALJ refused to allow any discussion or cross-examination. Then the ALJ spent half of his Initial Decision discussing this "evidence" that was accepted without any opportunity for response whatsoever by Respondents. This was an egregious violation of due process.

Complainants, with their Post-Hearing Brief, have included as Docket item G-31, an alleged FDA policy document. This document is presented, and relied upon, in rebuttal to testimony provided by Complainant's own witness, Mr. Devine. He testified, as described above, that FDA had no guidelines or standards indicating "when and how" CMPs were to be applied. Item G-31 was not presented by FDA prior to the hearing, as required, nor was it presented at the hearing. Accordingly, Respondents had no opportunity to review the document, and cross-examine the FDA's expert witness concerning the document. As pointed out above, the ALJ refused to even accept a proffered two-page Post Hearing Rebuttal Brief to address such issues.

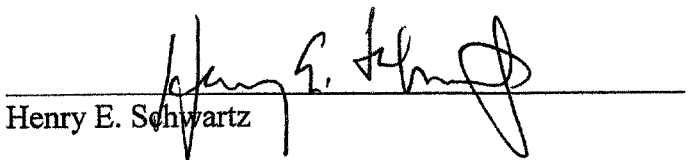
Complainants, with their Post-Hearing Brief, have included, as Docket items G-15-25, and 27-29, various documents allegedly demonstrating assets that in some fashion are allegedly under the past or current control of Respondent Korangy. These documents were not presented pre-hearing, or during the hearing, so Respondents had no opportunity to respond or cross-examine any witnesses regarding the allegations made with respect to these documents. Problems inherent in this lack of due process are exemplified by the fact that the documents present the alleged value of assets purported to be held by Respondents and Dr. Korangy's relatives. No mention is made of the mortgages/security interests on these assets that diminish their "value" to a small fraction of the alleged market value. No opportunity was presented to address issues such as this or the actual ownership of such assets.

Respectfully Submitted;

Henry E. Schwartz
Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
Towson, Maryland 21204
410. 938.8703
henryeschwartzllc@verizon.net

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of January, 2005, a copy of the foregoing Respondents' Memorandum was mailed, postage prepaid, to Marci Norton, Esquire, and Jennifer Dayok, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, MD 20857.



Henry E. Schwartz